

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SIMON BECKER, D.P.M.,

Plaintiff,

v.

THE HON. KATHLEEN SEBELIUS,
Secretary of the United States Department of
Health and Human Services, in her official
capacity,

Defendants.

Civil Action No.: 12-6177 (CCC)

OPINION

CECCHI, District Judge.

I. INTRODUCTION

This matter comes before the Court on the Motion of Plaintiff Simon Becker, D.P.M. (“Plaintiff”) for Summary Judgment [ECF No. 22], and on the Cross-Motion of Defendant Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services, (“Defendant” or “Secretary”) for Summary Judgment [ECF No. 25.] The motions are decided without oral argument pursuant to Rule 78 of the Federal Rules of Civil Procedure. For the reasons set forth below, Plaintiff’s Motion for Summary Judgment is denied and Defendant’s Cross-Motion for Summary Judgment is granted.

II. BACKGROUND

The parties’ dispute centers on the Secretary’s calculation, via extrapolation from a statistical sample, of Becker’s liability for overbilling Medicare for podiatry services. On July 9, 2009, Becker received a notice from Medicare contractor Highmark Medicare Services

(“Highmark”) informing him that he had been overpaid by Medicare. The basis of this notice was a determination made by Program Safeguard Contractor/Safeguard Services, LLC (“PSC”), in which the PSC reviewed a random stratified sample of claims from 65 beneficiaries (out of a universe of 979) within a relevant time period and then extrapolated the total amount of overpayment to the total number of beneficiaries.¹ The statistical sampling performed by the PSC revealed an error rate of 65.9%. While the PSC calculated the designated overpayment for the universe of beneficiaries to be \$747,361.67, it lowered the amount to \$656,624.83, claiming to take into account the lower limit of a two-sided 95% confidence interval. Highmark therefore requested a refund of \$656,624.83.

Becker’s counsel requested a redetermination from Highmark on July 30, 2009, and on December 1, 2009, Highmark wrote to Becker to advise him that the demand amount had been reduced to \$641,437.71. Becker next requested reconsideration by a qualified independent contractor (“QIC”) on December 9, 2009. The QIC issued a decision on February 8, 2010, finding favorably or partially favorably for Becker on some services but affirming most of the sample’s claim denials. As a result, Highmark wrote to Plaintiff on April 23, 2010 and requested a new total refund of \$631,953.94.

Subsequently, on March 2, 2010, Becker’s counsel appealed the QIC’s determination to an Administrative Law Judge (“ALJ”). The ALJ selected Dr. Harold Haller (“Haller”) as an

¹ The parties dispute the relevant timeframe for PSC’s review of medical records. Becker claims that the PSC reviewed records of beneficiaries between February 15, 2001 and February 25, 2004. (Pl.’s Statement of Undisputed Material Facts (“SMF”) ¶ 2.) The Secretary claims that the PSC reviewed records of beneficiaries between January 1, 2001 and December 31, 2003. (Def.’s SMF ¶ 4.)

independent expert in the field of statistics and sent him nine interrogatories.² Haller issued a report on June 21, 2010, in which he determined that the statistical sampling was invalid and noted that the PSC had not provided all of the information necessary for Haller to conduct a proper assessment. On June 25, 2010, the ALJ requested the information from the PSC that Haller identified as missing. Upon receiving additional information via the ALJ, Haller submitted an updated report on September 1, 2010, which again concluded that the sampling was invalid and claimed that he had still not received certain necessary information from the PSC. On March 31, 2011, the ALJ issued an Opinion invalidating the statistical sampling.

On May 26, 2011, the Centers for Medicare & Medicaid Services (“CMS”), through the QIC, requested that the Medicare Appeals Council (“MAC”) review the ALJ’s decision. After receiving a third report from Haller on June 11, 2011, the MAC vacated the ALJ’s decision and remanded the case for further proceedings, including a new decision. Specifically, the MAC found that “[while] the ALJ attempted to develop the record on the sampling issues . . . this effort fell short of his duty to develop a full and fair record.” (Dec. of Robert J. Corloy, Esq. “Conroy Dec.”, Ex. L.) The MAC found that the ALJ failed to provide the PSC with Haller’s initial written report and subsequent response to the PSC’s reply; erred in providing Haller with a CD of statistical sampling information provided by the PSC but failing to provide Haller with the PSC’s cover letter, which included Haller’s requested information; and failed “to provide any meaningful analysis or specific reasons for his decision with respect to sampling.” Id.

² The parties dispute whether Haller remained an independent expert throughout the appeals process. The Secretary claims that Haller was subsequently retained as an expert by Becker (Def’s SMF ¶¶ 32 and 59), while Becker maintains that Haller remained an independent witness throughout the proceedings (Pl’s SMF ¶ 10.)

On remand, Haller submitted an additional report, dated February 21, 2012.³ The PSC also supplemented the record with additional written and direct testimony of two of its statisticians, Dr. Timothy Champney and Cynthia Shen, MS, who addressed the objections to the statistically valid random sample methodology raised by Haller. After a hearing held on April 18, 2012, Haller submitted a fifth report dated April 20, 2012, reiterating that the sample was invalid. The ALJ issued a second Opinion on May 2, 2012, in which he concluded that “the sampling of [Becker’s] claims conducted by the PSC did not constitute a statistically valid random sample” and “that no overpayment for the services listed in Addendum A may be extrapolated to determine an overpayment for all of [Becker’s] claims initially paid by the Medicare Contractor for the time period under review.” (Conroy Dec., Ex. G.)

On June 28, 2012, CMS requested review by the MAC of the ALJ’s May 2, 2012 decision. The MAC issued an Opinion on September 4, 2012, in which it found that “the ALJ erred as a matter of law in concluding that the statistical sample as drawn and conducted in this case, and the extrapolated overpayment, are invalid ‘[b]ased on Dr. Haller’s findings as set forth in his report and in the hearing testimony’” (Conroy Dec., Ex. R.) Specifically, the MAC pointed out that:

The ALJ erred in relying upon Dr. Haller’s opinion that the statistical sample is invalid, as that opinion is based upon a statistical sampling treatise [called *Sampling Techniques*] that is not binding upon Medicare adjudicators and does not adequately consider the administrative authority set forth above, which permits more flexibility and imprecision in sampling than the standard statistical texts and treatises contemplate.

Id. The MAC further concluded that the ALJ’s decision was not supported by a preponderance of the evidence. First, while the ALJ relied on Haller’s claim that not all necessary information was

³ Notably, the Secretary argues that “[t]he higher mean values in Dr. Haller’s [February 21, 2012] report *increases* the overpayment estimate.” (Def’s Br. At 36.)

provided to him by the PSC, the MAC notes that all of the information requested by Haller could in fact be located “in the accompanying statistical sampling memorandum or on the CD of statistical sampling information that the ALJ provided to Dr. Haller” Id. Second, the MAC rejected Haller’s criticism that the sample size was “too small,” noting that such an allegation “is insufficient, standing alone, to invalidate sampling validity.” Id. Third, the MAC rejected the argument made by Haller that the sample was invalid because not all strata were normally distributed, noting that “Dr. Haller did not explain why each stratum must be normally distributed, why each stratum must individually have a large sample size, nor why 31 rather than four degrees of freedom must be applied to the sample.” Id. The MAC concluded that, because the probability sample design was properly executed and complied with the CMS Medicare Program Integrity Manual (“MPIM”), “assertions that the sample and its resulting estimates are ‘not statistically valid’ cannot legitimately be made.” Id. Becker filed a Complaint with this Court on October 2, 2012, seeking judicial review of the MAC’s decision pursuant to 42 U.S.C. § 1395ff(b)(1)(A) and 42 U.S.C. § 405(g). The decision of the MAC represents the final decision of the Secretary.

III. LEGAL STANDARD

A. Standard of Review of the MAC’s September 4, 2012 Opinion

A district court may set aside a final decision of the Secretary “only if it is ‘unsupported by substantial evidence,’ is ‘arbitrary, capricious, an abuse of discretion, or [is] otherwise not in accordance with the law.’” Mercy Home Health v. Leavitt, 436 F.3d 370, 377 (3d Cir. 2006) (alteration in original) (quoting 5 U.S.C. § 706(2)(A), (E)). “Substantial evidence has been defined as ‘more than a mere scintilla’; it means ‘such relevant evidence as a reasonable mind might accept as adequate.’” Hagans v. Comm’r of Soc. Sec., 694 F.3d 287, 292 (3d Cir. 2012) (quoting Plummer v. Apfel, 186 F.3d 422, 427 (3d Cir. 1999)). “Overall, the substantial evidence standard

is a deferential standard of review.” Jones v. Barnhart, 364 F.3d 501, 503 (3d. Cir. 2004) (citing Schaudek v. Comm’r of Soc. Sec. Admin., 181 F.3d 429, 431 (3d Cir. 1999)).

B. Summary Judgment

Summary judgment is appropriate if the “depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials” demonstrate that there is no genuine issue as to any material fact, and, construing all facts and inferences in a light most favorable to the non-moving party, “the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c); see also Celotex Corp. v. Catrett, 477 U.S. 317 (1986), Pollock v. Am. Tel. & Tel. Long Lines, 794 F.2d 860, 864 (3d Cir. 1986).

The moving party has the initial burden of proving the absence of a genuine issue of material fact. See Celotex, 477 U.S. at 323. Once the moving party meets this burden, the non-moving party has the burden of identifying specific facts to show that, to the contrary, there exists a genuine issue of material fact for trial. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986). In order to meet its burden, the nonmoving party must “go beyond the pleadings and by [its] own affidavits, or by the ‘depositions, answers to interrogatories, and admissions on file,’ designate ‘specific facts showing that there is a genuine issue for trial.’” Celotex, 477 U.S. at 324; see also Lujan v. Nat’l Wildlife Fed’n, 497 U.S. 871, 888 (1990) (stating that “[t]he object of [Rule 56(e)] is not to replace conclusory allegations of the complaint... with conclusory allegations of an affidavit.”); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986); Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992), cert. denied, 507 U.S. 912 (1993) (stating that “[t]o raise a genuine issue of material fact,” the opponent must “exceed the ‘mere scintilla’ threshold...”). A fact is “material” if a dispute about that fact “might affect the outcome of the suit under governing [substantive] law,” and a “genuine” issue

exists as to that fact “if the evidence is such that a reasonable jury could return a verdict for the non[-]moving party.” Anderson, 477 U.S. at 248. The Court’s role is to determine whether there is a genuine issue for trial, not to weigh the evidence and decide the truth of the matter. Id. at 249.

IV. DISCUSSION

Becker argues that this Court must reverse the decision of the MAC, which found that the statistical sample and overpayment extrapolation were valid. Becker asserts that the MAC’s decision “is founded upon an extrapolation which is, from a scientific and statistical standpoint, completely worthless, and therefore cannot form ‘substantial evidence’ to support the decision.” (Pl’s Br. at 8.) Becker begins by noting that the ALJ’s findings “were thoroughly reasoned and amply supported by substantial evidence” and that “there has been absolutely no showing that the ALJ, in any way, abused his discretion in reaching his conclusions or that he premised his findings upon legally erroneous standards.” Id. at 4. This argument, however, mischaracterizes the standard of review that must be applied by the MAC. As recently explained by the Third Circuit, “Although MAC is limited to considering only the record before it, its review of the ALJ’s findings is *de novo* and MAC ‘is not obligated to defer to the outcomes of prior decisions below.’” Balko & Assocs., Inc. v. Sec. of U.S. Dept. of Health & Human Servs., No. 13-1568, 2014 WL 542262, at *5 (3d Cir. Feb. 12, 2014) (quoting Almy v. Sebelius, 679 F.3d 297, 310 (4th Cir. 2012)). Thus, “inasmuch as we are concerned on this appeal . . . with a review of MAC’s decision, we do not review the ALJ’s findings, and [Plaintiff’s] arguments addressing those findings are irrelevant.” Id.

Apart from his bolstering of the ALJ’s decision, Becker offers several arguments as to why “the extrapolation performed by the PSC was fundamentally and fatally flawed,” relying exclusively on the opinion of Haller for support. Id. at 5. Becker asserts that “the PSC failed to

prove that the distribution of the mean was normal,” and that “the PSC failed to retain adequate data regarding the beneficiaries in each stratum.” *Id.* at 5-6. The MAC, however, adequately addressed these same arguments within its decision and determined that the statistical sample was valid. After setting forth the MPIM requirements that a Medicare contractor must follow in conducting a statistical sample, the MAC reviewed the evidence on which it based its decision, carefully laying out the basis of the PSC’s probability sample and overpayment determination with citations to the record, and determined that “CMS has chosen a reasonable, feasible, and well-articulated approach for collecting overpayments which, by design, offsets precision in favor of lower recovery amounts.” (Conroy Dec., Ex. R.) The Court has reviewed the citations provided by the MAC and finds that they support the factual background set forth by the MAC. Further, as the MAC explains in its decision, “given MPIM provisions, the fact that a PSC selected a sampling methodology or sample size that another statistician may not prefer, or which may not result in the most precise point estimate, does not provide a basis for invalidating the sampling or the extrapolation as drawn and conducted *in this case*.” *Id.* See Balko, 2014 WL 542262, at *5 (noting that because the PSC in that case had “complied with applicable Medicare rulings and the MPIM, [the plaintiff] bore a heavy burden of showing that the sample was statistically invalid, and not merely that another statistician might construct a different or more precise sample”).

Finally, the Court notes that Becker incorrectly asserts that “[o]nce Dr. Becker has offered a reasoned basis for why the statistical sample is invalid, it most certainly is the role and responsibility of PSC and AdQIC to demonstrate its validity.” (Pl’s Br. at 9.) Becker asserts that the PSC did not provide evidence that the statistical sample was valid, apart from opinions of its own staff, and that the PSC did not proffer evidence to dispute Haller’s reports. It is clear, however, that the burden in fact rests on Becker to prove the invalidity of the statistical sampling

and extrapolation, and not on the PSC or QIC. Balko, 2014 WL 542262, at *5; Maxxim Care EMS, Inc. v. Sebelius, Civ. Action No. H-10-1408, 2011 WL 5977666, at *3 (S.D. Tex. Nov. 29, 2011) (noting that the plaintiff challenging the Secretary's final decision regarding the statistical sampling "had the burden to prove the invalidity of the statistical sampling and extrapolation"). According to the MAC, Becker failed to meet that burden. Given the deferential standard of review that this Court must apply, and having carefully reviewed the record and the MAC's determinations, the Court finds that the MAC's decision was supported by substantial evidence.

V. CONCLUSION

For the reasons set forth above, Becker's Motion for Summary Judgment is denied and the Secretary's Motion for Summary Judgment is granted. An appropriate Order accompanies this opinion.

DATED: June 13, 2014


CLAIRE C. CECCHI, U.S.D.J.